**No. 19-71324**

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents.

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# RESPONDENTS' OPPOSITION TO PETITION FOR A WRIT OF MANDAMUS

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## INTRODUCTION

Petitioner Natural Resources Defense Council ("NRDC") contends that the United States Environmental Protection Agency ("EPA") has unreasonably delayed responding to NRDC's April 23, 2009 Petition Requesting Cancellation of All Pet Uses of Tetrachlorvinphos ("Petition"). NRDC Appendix ("NRDC App.") at 28. Tetrachlorvinphos, commonly referred to as "TCVP," is a pesticide used in flea collars and shampoos for dogs and cats.[1] NRDC maintains that pet products containing TCVP pose an unreasonable risk to persons, particularly children, who come into dermal contact with pets treated with such products. Petition at 6. NRDC has requested that EPA cancel immediately all registrations for pet products containing TCVP, which would bar all sales of such products.[2] *Id.*

As explained below, and in the accompanying declaration, EPA is diligently working towards reaching a scientifically-sound decision concerning whether pet products containing TCVP pose an unreasonable risk to persons, and has not

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[1] TCVP is used for other purposes, but NRDC's Petition addresses only the use of TCVP in products for household pets.

[2] As explained in more detail *infra* at 6-7, 25-26, EPA cannot cancel FIFRA registrations through a petition response. FIFRA sets forth a specific process, including an adjudicatory proceeding if requested by the registrant, that EPA must follow to cancel a registration. 7 U.S.C. § 136d; *see also* 40 C.F.R. Pt. 164. If EPA ultimately decides that NRDC's arguments have merit, the most EPA could do in response to the Petition would be to conclude that the Agency should initiate the statutory cancellation process.

unreasonably delayed responding to the Petition. The Agency identified the study that the only remaining registrant for these products had to perform to provide EPA with the remaining information necessary to its decision. After efforts to work cooperatively with the registrant failed, the Agency used its statutory authority to compel the registrant to submit the study at issue. This exercise of authority demonstrates EPA's commitment to completing this process. The registrant has just submitted a report that may adequately address the Agency's remaining issue. The Agency is moving forward with the process of evaluating the report so that the results, if scientifically acceptable, can be used to complete the necessary risk assessment.

The public interest, including the interests of NRDC, will be best served if EPA is allowed to complete its ongoing review of TCVP registrations and preparation of the Petition response. NRDC's goal is to have the registration cancelled. While EPA takes no position at this time on that ultimate question, the Agency must ensure that there is a sound scientific basis for any decision it may make. If EPA fails to give proper consideration to the results of the study that it compelled the registrant to produce, any decision with respect to cancellation would likely not fare well either in an administrative hearing or upon judicial review. Therefore, EPA must be allowed sufficient time to address the study, to

require Hartz to remedy any deficiencies therein, and complete its analysis before acting on the Petition.

As further relevant context here, EPA did previously answer NRDC's Petition in 2014. EPA, Response to NRDC's April 23, 2009 Petition Requesting Cancellation of All Pet Uses of TCVP (Nov. 6, 2014) ("2014 Response"). NRDC App. 61-72. Before responding, EPA conducted an updated risk assessment to evaluate non-occupational residential exposure for all TCVP pet products. *Id.* at 1. EPA concluded that this assessment, as well as the other information discussed by EPA, showed that "all identified risks associated with TCVP pet uses (including pet collars) result in risks that are below the Agency's level of concern." *Id.* at 12. Therefore, EPA denied NRDC's Petition.

NRDC then sought judicial review of EPA's final action. *NRDC v. EPA*, No. 15-70025 (9th Cir.) ("Case No. 15-7002"). In that litigation, EPA moved for a voluntary remand to allow the Agency to reconsider its final decision in light of new information being developed as EPA worked on a new health risk assessment. That health risk assessment was part of the Agency's review of all TCVP registrations, including the pet products of concern to NRDC. This "registration review" is required by the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(g). This Court granted EPA's motion for remand on June 9, 2016. Order (June 9, 2016). Dkt. Entry 30.

Given that EPA previously took action to deny the Petition in 2014, and that the Court in June 2016 remanded the response to allow for additional Agency assessment, the question before the Court on this petition for writ of mandamus is whether the Agency has egregiously delayed reconsidering its response to the Petition following the Court's remand in 2016. For the reasons set forth below, the Agency has *not* egregiously delayed its response. EPA has proceeded appropriately to address complicated scientific issues. If, however, the Court should conclude that the extraordinary remedy of a writ of mandamus is warranted, the Court should allow the Agency until September 2021 to complete its response.

EPA is currently working on the review of all TCVP registrations required by FIFRA, 7 U.S.C. § 136a(g)(1)(A)(iii). EPA anticipates that the penultimate step in this process, referred to as the Interim Decision, will be completed in September 2021. At that point, EPA will also have information necessary to respond to the Petition. The Agency intends to issue its response at the same time as the Interim Decision. This approach is the most efficient for the Agency; will avoid a delay in the registration review; and avoids the potential that developments in the registration review would require the Agency to revise its response to NRDC's Petition. *See* Declaration of Dr. Mary Elissa Reaves, Acting Director of the Pesticide Re-evaluation Division, Office of Pesticide Programs, EPA, ¶ 39 (Sept. 5, 2019) ("Decl."). Attachment 1. If the Court is to grant NRDC any relief, the

Court should allow the Agency to continue addressing the TCVP registration review and the Petition in one process and respond to the Petition in September 2021.

## BACKGROUND

## I. STATUTORY BACKGROUND

### A. FIFRA and Pesticide Registration

FIFRA, 7 U.S.C. §§ 136-136y, requires EPA approval of pesticides prior to their distribution or sale, and establishes a registration regime for regulating the use of pesticides. *Id.* § 136a(a), (c). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id.* § 136a(c)(5); *see also id.* § 136(bb).

FIFRA requires that EPA must periodically review the pesticide registrations. 7 U.S.C. § 136a(g)(1)(A)(iii). The process EPA uses for evaluating the potential for health and ecological effects of a pesticide is called risk assessment, which is part of a risk management process. In registration review, that risk assessment typically includes an ecological risk assessment, a human health risk assessment, and, when appropriate, a cumulative risk assessment (evaluating the risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes of exposure to a group of chemicals that share a common mechanism of toxicity).

The initial review must be completed within 15 years after the first pesticide containing a new active ingredient is registered, but not later than October 1, 2022. *Id.* Registration review cannot result in the cancellation of a particular registration. *Id.* § 136a(g)(1)(A)(v). Instead, if EPA determines that a pesticide does not meet the standard for registration, EPA must comply with the requirements of section 136d to proceed to seek cancellation. *Id.*

EPA has promulgated regulations that establish the procedures to be used in registration review. 40 C.F.R. Pt. 155, Subpt. C. These include a process by which EPA can meet with stakeholders to discuss issues such as possible risk mitigation options. *Id.* § 155.52. Where EPA determines that a new risk assessment is appropriate, a draft must be prepared and published for public comment on both the risk assessment and any possible risk mitigation options. *Id.* § 155.53. EPA will then prepare a proposed Interim Decision. *Id.* § 155.56. In this proposed decision, the Agency must:

> (1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.
>
> (2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.
>
> (3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.
>
> (4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

*Id.* § 155.58(b). After allowing for a public comment period of at least 60 days, the Agency will issue the final Interim Decision. *Id.* § 155.58(c). If the registrant does not comply with the terms of the final Interim Decision, EPA "may take appropriate action under FIFRA." *Id.* § 155.58(d). Such action may include initiating cancellation proceedings.

As is clear from its name, the Interim Decision is not the end of the registration review process. It is, however, the last step necessary for EPA to resolve all issues pertaining to the NRDC Petition. Therefore, EPA will not address the remaining steps in the review process.

**B. Cancellation**

Under FIFRA, a registrant can request the voluntary cancellation of a registration pursuant to the procedures in section 136d(f). EPA must provide notice and a period for public comment before granting such a request. 7 U.S.C. § 136d(f)(1).

In relevant part, FIFRA section 136d(b) authorizes EPA to initiate cancellation proceedings "[i]f it appears to the [Agency] that a pesticide . . . generally causes unreasonable effects on the environment." EPA can issue a notice of intent to either: (1) cancel the registration; or (2) hold a hearing to decide whether the registration should be cancelled. *Id.* Before issuing such a notice,

EPA must consider a series of factors identified in the statute and complete a prescribed process for allowing the Secretary of the Department of Agriculture ("USDA") and the FIFRA Scientific Advisory Panel (a group of scientists charged with providing EPA with advice related to pesticide actions) to comment on the proposed notice. *Id.*; *see also id.* § 136w(d). EPA must publish in the Federal Register the proposed notice; any comments from Agriculture; and EPA's response to such comments. *Id.* § 136d(b). After the notice is issued, the registrant may request an evidentiary hearing before a hearing examiner. Any order to cancel or revise the registration must be "based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based." *Id.* § 136d(d). Where EPA determines that the Agency must act immediately to avoid imminent harm, the Agency can suspend the registration for the duration of the cancellation proceedings pursuant to the procedures in section 136d(c).

### C. Petitioning EPA

FIFRA does not establish a process for petitioning EPA to take action with respect to a particular registration. A party may, however, petition EPA to take such action under the Administrative Procedure Act ("APA"). The APA requires that the agencies must complete their work "within a reasonable time" and

provides a judicial remedy if the agency unreasonably delays responding to the petition. 5 U.S.C. §§ 555(b), 706(2)(B).

## II. FACTUAL BACKGROUND

### A. The Pesticide

TCVP is a member of the organophosphate class of pesticides that act by inhibiting the enzyme acetylcholinesterase. This pesticide was first registered in 1966 and is primarily used on livestock and pets to control insects like fleas. In 2006, EPA reregistered TCVP after conducting a residential risk assessment for exposures to TCVP and a cumulative risk assessment for exposures to all organophosphates. Decl. ¶ 4.

### B. NRDC's Petition and Prior Litigation

NRDC submitted its Petition asking EPA to cancel all registrations for pet uses of TCVP in pet products on April 23, 2009.[3] Before responding, EPA conducted an updated risk assessment to evaluate non-occupational residential exposure for all TCVP pet products. 2014 Response at 1. The Agency completed this assessment on November 5, 2014. "Residential Exposure Assessment in

[3] In 2014, NRDC filed a petition for a writ of mandamus asking the D.C. Circuit to order EPA to respond to the petition within 60 days. *In re Natural Resources Defense Council*, Case No. 14-1017, Doc. 1478697 (D.C. Cir. Feb. 6, 2014). NRDC and EPA filed a joint motion to dismiss this matter pursuant to Fed. R. App. 42(b) after the EPA Response was issued. Joint Motion to Dismiss, *In re Natural Resources Defense Council*, Case No. 14-1017, Doc. 1523854 (Nov. 21, 2014). The Joint Motion was granted by Order dated December 9, 2014.

Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for Tetrachlorvinphos" ("2014 Pet Products Assessment"). *See* Decl. ¶ 11. EPA concluded that this assessment, as well as the other information discussed by EPA, showed that "all identified risks associated with TCVP pet uses (including pet collars) result in risks that are below the Agency's level of concern." 2014 Response at 12. Therefore, EPA denied NRDC's Petition. *Id.*

Following EPA's 2014 action denying its administrative Petition, NRDC petitioned this Court for review of EPA's final action. *Natural Resources Defense Council v. EPA*, Case No. 15-70025 (9th Cir.). During that litigation, EPA moved the Court for a voluntary remand so that the Agency could reconsider its response after completing a new risk assessment for all TCVP products as part of the ongoing registration review process. *Id.*, Dkt. Entry: 22-1 (Sept. 25, 2015). That risk assessment was being conducted independently from the litigation on the denial of NRDC's administrative Petition, but EPA anticipated that it would consider many of the scientific issues that had been raised by NRDC in the litigation. EPA further anticipated that the new risk assessment would likely differ in a number of ways from the earlier risk assessment relied upon by EPA in denying NRDC's administrative Petition. Decl. ¶ 13. EPA therefore sought voluntary remand without vacatur in the litigation, which the Court granted on

June 9, 2016. Order (June 9, 2016), Dkt. Entry 30.[4] In the course of seeking a remand, EPA represented that the Agency "intends to issue a revised response to NRDC's petition within 90 days after finalizing the risk assessment." Dkt. Entry 26 at 10.

### C. The Revised Risk Assessment

Following remand, EPA issued the revised risk assessment for TCVP on December 21, 2016. EPA, Revised Human Health Risk Assessment for Registration Review, NRDC App. 170. ("Revised Risk Assessment"). The Revised Risk Assessment, in part, addressed an issue that had been first raised by NRDC in its petition for review of EPA's 2014 Response: whether a person handling a pet wearing a flea collar would be exposed to TCVP in a powder or liquid form. *Id.* at 50-51. EPA had previously treated the pet collars as releasing the TCVP as a liquid formulation because the substance was spread from the collar over the animal's coat by the animal's natural skin oils. *Id.* at 52. Information submitted by NRDC and by Bayer HealthCare (a former registrant),[5] however,

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[4] The Court initially denied this motion, but allowed leave to renew after the draft risk assessment was published. Dkt. Entry: 25 (Dec. 16, 2015). On February 11, 2016, after the draft assessment was published at 81 Fed. Reg. 3128 (Jan. 20, 2016), EPA did renew its motion for remand. Dkt. Entry 26.

[5] Bayer, which did not have any flea collars or other pet products on the market, has voluntarily cancelled its registrations. *See* Regulations.gov, EPA ID: EPA-HQ-OPP-2008-0316-0076.

showed that consideration should also be given to exposure to a powder formulation because the TCVP could be in powder form in the immediate area of the collar on the pet. *Id.*

As explained more fully in the accompanying declaration of Dr. Mary Elissa Reaves, the lack of definite information regarding the nature of the formulation presented a complication for purposes of risk assessment. Decl. ¶ 20. As explained by Dr. Reaves, in the December 2016 risk assessment, EPA had applied assumptions of varying liquid/dust ratios in the collar to account for uncertainty:

> [EPA] assessed pet collars using *assumptions* of varying ratios of liquid/dust in the collar in the exposure calculations to account for this current *uncertainty* in order to assess the impact it could have on the outcome of the assessment. . . . In the December 21, 2016 Revised Human Health Risk Assessment, risk estimates are provided assuming several different liquid/dust ratio formulations (1/99, 50/50, and 99/1). The 2016 Revised Human Health Risk Assessment indicates that there is at least a 60-fold difference between the liquid/dust ratio of 99/1 and 1/99 liquid/dust ratio; the more TCVP that is in liquid form, the lower the risk concern.

*Id.* (emphasis in the original). Thus, the 2016 analysis reflected that the risks would be substantially lower if most of the TCVP is released from the collar in liquid form than if the TCVP is released from the collar in dust form. *Id.*

The 2016 risk assessment did indicate that exposure to pets with TCVP collars were estimated to be of concern for the most highly-exposed sub-population (children between 1 and 2 years of age) regardless of the ratio of liquid to dust assumed. NRDC App. at 179. This evaluation also specified the Agency's

intention "to request and review additional information relating to all registered pet collar products as they undergo registration review, as well as any proposed new pet collar uses." *Id.* at 222. Furthermore, it specified that "this evaluation will continue until the agency is satisfied that, based on the design and operation of pet collar products, a final formulation type decision can be made along with recommendations for human health risk assessment of exposures to pet collar-treated pets." *Id.* In short, the Agency was clear that the risk determination could change in a new risk assessment, and that the Agency anticipated conducting it only once the physical form of TCVP being released from pet collars was known. However, even if the new risk assessment continues to show risks of concern regardless of the form of material leaving the collars, the risk differential between the liquid form and dust form could well be significant.

Regulatory decisions under FIFRA are subject to a risk-benefit standard. When EPA applies that standard, it first performs risk assessments to determine whether there are any risks of concern. If the assessment identifies risks of concern, EPA then must make a risk-management decision determining what, if anything, needs to be done to address the risks of concern. Decl. ¶ 22. Because FIFRA calls for a risk-benefit standard, EPA can look at whether the benefits of a pesticide justify the risks associated with the pesticide; a pesticide causing risks of concern can meet the FIFRA standard if the pesticide use results in sufficient

benefits. Even where risks of concern are determined not to be justified by benefits, EPA looks carefully at whether registration changes can sufficiently mitigate risks of concern either to allow EPA to conclude that the benefits now outweigh the (mitigated) risks, or that the mitigated risk no longer exceeds the level of concern. The greater the level of risk, and the more the assessed level of risk exceeds EPA's level of concern, the harder it becomes for EPA to either make a positive risk-benefit determination allowing the registration to continue or to mitigate the risk to get it below the "risk of concern" level and the less likely it becomes that alternatives to cancellation can be found. *Id.*

### D. EPA's Actions After Completing The Revised Risk Assessment

Although EPA had anticipated, in moving for a voluntary remand in the previous litigation, that it would be in a position to respond fully to NRDC's administrative Petition within 90 days after issuing the final revised Human Health Risk Assessment, with the considerable remaining uncertainty regarding the formulation of TCVP in pet collars and associated exposure risks, the Agency has been unable to do so. Decl. ¶ 21. On March 21, 2017 (90 days after completion of the 2016 risk assessment), the Agency informed NRDC that EPA instead intended to address risk-mitigation issues related to the use of TCVP in pet products as part of the ongoing registration review of all TCVP Registrations. Letter from Yu-Ting

Guilaran, Director, Pesticide Re-evaluation Division, Office of Pesticide Programs, EPA (Mar. 17, 2017). NRDC App. 386.[6]

Following completion of the 2016 risk assessment, EPA has been endeavoring to secure additional data regarding the formulation of the releases from the pet collars from Hartz Mountain Corp., the only remaining pet collar registrant, which will allow EPA to provide necessary refinement to the TCVP post-application risk assessment. Decl. ¶ 24. Specifically, EPA has concluded that the best means of determining the form of TCVP released from the collars is through a mechanical torsion study where the collar is twisted and stretched repeatedly to exaggerate the movement of the collar against the animal. Decl. ¶ 23. This ensures that the active ingredient is released in order to measure the maximum amount of dust that can be released from a pet collar. *Id.*

EPA held several discussions with Hartz in 2017 in an effort to have the registrant perform such a mechanical torsion study. Decl. ¶ 24. *See also* NRDC App. 395, 397-98 (EPA notes of teleconferences with Hartz on July 11 and August 7, 2017). Hartz, however, initially declined to perform the torsion study on the ground that the form of residues released from the collar could be alternatively

[6] EPA originally planned to complete the comprehensive review of TCVP registrations in 2017. *See* NRDC Pet. at 12 (citing EPA's 2017 Registration Review Schedule for Conventional Cases (Feb. 9, 2017)). However, as set forth below and in the accompanying declaration, EPA currently estimates the review can be completed in 2021.

determined through an analysis of the physical chemical properties of the ingredients in the collar formulation. Decl. ¶ 25. While Hartz has provided a number of exposure studies to EPA since 2017, all are predicated on the position that the TCVP pet collar behaves as a liquid. *Id.* Although EPA is reviewing the data presented by Hartz, the Agency continues to believe that a mechanical torsion study is needed. Accordingly, EPA issued a Data Call-In to Hartz on June 3, 2019, pursuant to FIFRA, 7 U.S.C. § 136a(c)(2)(B)(i), for the performance of the torsion study.

Under section 136a(c)(2)(B)(ii), Hartz had 90 days from June 3, or until Tuesday, September 3, 2019, to "provide evidence" that it is gathering the requested data or EPA could issue a notice to suspend Hartz's registration. The Data-Call-In further required Hartz to complete the torsion study and submit the final report to EPA within six months (before March 1, 2020). *See* Decl. ¶ 26 (explaining why six months is a reasonable time period for this task). If the deadline was not met, EPA could issue a notice of intent to suspend the registration under section 136a(c)(2)(B)(iv).

On August 28, 2019, Hartz provided a response to the Data Call-in in which it committed to conducting the torsion study. Decl. ¶ 28. Along with that response, Hartz submitted a torsion study, but without first having submitted a study protocol to the Agency for review, a step that had been required by EPA in

the Data Call-In. Because EPA did not have an opportunity to review and approve the protocol before the study was performed, the Agency expects that it will take up to six months, or until March 1, 2020, to review the protocol used by Hartz and to allow Hartz, if necessary, to address any inadequacies or conduct a new study.

## STANDARD FOR REVIEW

With respect to mandamus requests, "[m]andamus is an extraordinary remedy and one that will be employed only in extreme situations." *Clorox Co. v. U.S. Dist. Court for N. Dist. of Cal.*, 779 F.2d 517, 519 (9th Cir. 1985) (citations omitted). The circumstances that will justify interference with non-final agency action must be truly extraordinary, because this Court's supervisory province as to agencies is not as direct as its supervisory authority over trial courts. *Pub. Util. Comm'r of Or. v. Bonneville Power Admin.*, 767 F.2d 622, 630 (9th Cir. 1985). The party seeking a writ of mandamus bears the burden of proving that its right to issuance of the writ is "clear and indisputable." *In re Cal. Power Exch. Corp.*, 245 F.3d 1110, 1120 (9th Cir. 2001) (internal quotation marks and citation omitted).

## ARGUMENT

### I. EPA HAS NOT UNREASONABLY DELAYED RECONSIDERING ITS PRIOR RESPONSE TO NRDC'S PETITION

EPA has not unreasonably delayed reconsidering its prior response to NRDC's petition. "Mandamus is warranted in those rare instances when the agency's delay is egregious." *In Re Pesticide Action Network NA* ("*PANNA*"), 798

F.3d 809, 813 (9th Cir. 2015) (internal quotation omitted). *In re Cal. Power Exch. Corp.*, 245 F.3d at 1120, establishes that this Court will apply the six-factor standard articulated in *Telecommunications Research and Action Center v. F.C.C.*, 750 F.2d 70, 79-80 (D. C. Cir.1984) ("*TRAC* factors."). These factors are:

> (1) the time agencies take to make decisions must be governed by a rule of reason;
>
> (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;
>
> (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
>
> (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;
>
> (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and
>
> (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

*PANNA*, 798 F.3d at 813 (quoting *TRAC*, 750 F.2d at 79-80).

Not every *TRAC* factor will be relevant in each case. Here, because FIFRA does not provide any indication of a timeframe for the Agency to respond to the NRDC Petition, the second factor is not relevant. In addition, the final factor need not be addressed; EPA acknowledges that the Court need not find any impropriety

to grant relief if otherwise warranted. The remaining factors are addressed below, and applying these factors, NRDC's mandamus petition should be denied.

### A. The Agency's Progress Subsequent To the 2016 Remand Has Been Reasonable.

EPA has not unreasonably delayed reaching a reconsidered decision on NRDC's Petition. As an initial matter, NRDC's suggestion that the Court should evaluate the Agency's progress over the entire ten years since its Petition was first filed in 2009 is misplaced. This ignores that EPA did previously meet its duty to respond to the Petition by providing a final response in 2014. Subsequently, the Court granted EPA's request to remand the 2014 Response so that the Agency could consider its decision again in light of the new information that would be developed under the Revised Risk Assessment to be performed in conjunction with the overall TCVP registration review. *Natural Resources Defense Council*, Case No. 15-70025 Dkt. Entry 30. The Court simultaneously denied NRDC's motion to vacate the 2014 Response. *Id.* *See also supra* at 9. Accordingly, the question before the Court is narrow in scope: namely, has EPA egregiously delayed completing its reconsideration of the 2014 Response? It has not.

The Declaration of Dr. Reaves reflects that the Agency's timetable for completing its reconsideration of EPA's prior response is reasonable. As explained in the Declaration, with the remaining uncertainty around the physical form of TCVP present in the pet collars (i.e., whether the TVCP in pet collars

behaves as a liquid or a solid), the Agency has been unable to fully respond to NRDC's administrative petition. Decl. ¶¶ 19-22. The Revised Risk Assessment issued by the Agency in December 2016 did not resolve this uncertainty. *Id.* ¶¶ 21-22.

After release of the Revised Risk Assessment, the Agency has determined that the optimal method for reducing the uncertainty relating to the physical form of TCVP is to require the registrant to conduct a composition study in the form of a mechanical torsion test. *Id.* ¶ 23. The Agency has also taken steps to assure that such a study is performed. After discussions with Hartz to secure the registrant's agreement to perform such a composition study were unsuccessful—which would have been the most efficient pathway for completion of the study—the Agency issued the Data Call-In to Hartz on June 3, 2019 to compel Hartz to complete the torsion test and to submit a final study to EPA. Hartz did submit a study on August 28, 2019, but did not first submit a required protocol for EPA review; EPA has not yet determined whether the submitted study is an appropriate response to the Data Call-In. *Id.* ¶ 28.

Thus, in the period since the Revised Risk Assessment was issued in December 2016, EPA has identified the remaining uncertainty that must be resolved prior to acting on NRDC's Petition (i.e., the physical form of TCVP in pet collars) and decided upon the method by which the information to address that

uncertainty can be gathered (i.e., the torsion study). EPA reasonably sought Hartz's voluntary agreement to perform the study since such cooperation would have expedited the process. When that effort failed, EPA used its statutory authority to compel Hartz to complete the necessary test. These efforts represent a reasonable amount of progress to date towards the goal of completing reconsideration of the 2014 Response. Now that Hartz has made a submission, if the Agency finds that the study was properly performed, the Agency can move forward to complete its process.

### B. The Remaining Relevant TRAC Factors Weigh in EPA's Favor.

*TRAC* explained that "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake." 750 F.2d at 80. As this Court has previously noted, this *TRAC* factor is of limited use in evaluating delays by EPA because "EPA, by its nature, regulates almost entirely in the realm of human health and welfare." *In Re Pesticide Action Network* NA, 532 Fed. Appx. 649, 651 (9th Cir. 2013). Accelerating one action by EPA can serve to delay other actions that also impact human health and welfare. *Id.* (citing *Sierra Club*, 828 F.2d 783, 798 (D.C. Cir. 1987)).

*TRAC* also requires the Court to consider "the effect of expediting delayed action on agency activities of a higher or competing priority" and the "nature and extent of the interests prejudiced by delay." 750 F.2d at 80. The competing

priorities here are the more than 300 pesticide registration reviews that must be completed by EPA by October 2022 to meet the statutory deadline imposed by FIFRA. Decl. ¶ 29; 7 U.S.C. §136a(g)(1)(A)(iii)(I). While NRDC contends that the lack of a more expeditious reconsideration of the 2014 Response poses a risk to the health of children, NRDC does not establish that the TCVP in pet products poses a greater risk to health than the hundreds of other pesticides for which EPA is reviewing the registrations, or than other uses of TCVP. Thus, giving NRDC's Petition undue precedence over the registration reviews may be detrimental to overall protection of human health from pesticides. Accordingly, these factors do not weigh in favor of granting the petition for writ of mandamus, much less requiring EPA to reconsider the 2014 Response in 60 days.

## II. EPA HAS A REASONABLE PLAN TO DEVELOP THE RESPONSE TO THE NRDC PETITION IN THE COURSE OF PREPARING THE INTERIM DECISION FOR THE TCVP REGISTRATION REVIEW

EPA has a reasonable plan in place to complete its response to this Court's 2016 remand and conclude reconsideration of its prior response to NRDC's petition. As explained by Dr. Reaves, the most efficient course for the Agency is to complete its petition response as part of the ongoing TCVP registration review. Decl. ¶¶ 29-38. In particular, inefficiencies will be avoided if EPA can include the pet products in the risk assessment to be developed as part of the ongoing TCVP registration review because otherwise the Agency will have to conduct two

separate risk assessments, resulting in duplicative efforts. *Id.* ¶ 31. These inefficiencies will be increased if the same individuals are not available to work on each of the separate reviews. *Id.* Avoiding these inefficiencies will allow the Agency to more effectively complete all of its obligations with respect to reviewing TCVP registrations, as well as the many other registrations that must be addressed by October 22, 2022. *Id.* ¶ 29.

Moreover, to complete the Interim Decision, EPA must conduct an aggregate assessment of all risks from TCVP exposure. This aggregate assessment may result in changes to EPA's conclusions regarding the status of the pet use registrations. *Id.* ¶ 37. Finally, the public may submit comments on the registration review that address the pet use registrations. Such comments may raise new issues that may require changes to the risk assessment for the pet uses. *Id* ¶ 36.[7]

EPA estimates that if the pet uses can be addressed as part of the overall registration review, EPA will be able to respond to the NRDC Petition and issue the Interim Decision in the registration review by September 2021. *Id.* ¶ 32. This

[7] The Agency believes it beneficial to take comment on its regulatory decisions both to determine whether stakeholders or the public have additional information that warrants appropriate revisions to the decision, and to allow members of the public to participate in the regulatory process (which has a value of its own). Decl. ¶ 36.

is approximately 18 months after March 1, 2020, which is when EPA expects to have completed its evaluation of the protocol used by Hartz in preparing the torsion study and any necessary corrections have been made.[8] *Id.* ¶ 37. This 18-month period breaks down as follows:

- Three months to determine whether the completed study is scientifically acceptable;
- Three months to prepare a revised risk assessment for all TCVP registrations;
- Two months for public comment on the revised risk assessment;
- Six months for the Agency to address comments on the risk assessment; to hold discussion with stakeholders on possible mitigation requirements; and to prepare a proposed Interim Decision for public comment;
- Two months for comment on the proposal;
- Two months to prepare the responses to comments, the final Interim Decision, and the response to the NRDC Petition.

*Id.* ¶ 32.

As noted above, by using the same process to develop the Interim Decision to also resolve the issues in the NRDC Petition, the Agency can avoid duplicative steps, such as preparing two risk assessments. Moreover, the opportunities for public comment and meeting with stakeholders may result in proposals regarding risk mitigation requirements applicable to the pet products registrations that could affect the Agency's decision on the NRDC Petition. Decl. ¶ 36. For example, if

[8] If, after reviewing Hartz's torsion study, the Agency finds it acceptable, these timeframes may be shortened by two or three months. Decl. ¶ 29 n.1.

lowering the limit on TCVP in a product would resolve any human health risks that may be identified and the registrant is willing to apply for an amendment to the registration, the Agency could conclude NRDC's Petition by starting the process to amend a registration, rather than to cancel it. *Id.* ¶ 38. Finally, it would ensure that the effect of pet products on the aggregate risk posed by all TCVP uses was considered before a petition response was issued. *Id.* ¶ 37.

As explained by Dr. Reaves, EPA's conclusion on the aggregate risk analysis could cause a change in the Agency's approach to the pet product registrations. *Id.* The aggregate risk analysis is required under the Federal Food, Drug and Cosmetic Act ("FFDCA") when EPA evaluates whether pesticide tolerances (regulations establishing allowable residues of pesticides in food products) for TCVP meet the "reasonable certainty of no harm standard" established by the FFDCA. *Id.*; *see* 21 U.S.C. § 346a(b)(2)(A)(ii). Tolerances are required for pesticide uses that result in residues in food. While the pet care uses of TCVP do not require tolerances, there are other registered uses of TCVP on cattle, swine, and poultry that do require tolerances. If the pet products are considered in isolation, no aggregate assessment would be required because there is no dietary exposure involved. *Id.* ¶ 37. In reviewing some of the other TCVP registrations, which would happen during the registration review process, EPA would have to consider the aggregate (total) exposure for people who receive

exposure to TCVP both from pet products and those uses that result in dietary exposure. If the aggregate risk exceeds the "reasonable certainty of no harm" standard established in the FFDCA, EPA may decide that the most effective or appropriate means to reduce the aggregate risk is by imposing modifications to the pet use products that would not be necessary if the registrations for those products were considered in isolation. *Id.*

Moreover, while the pet use is an important component of the TCVP use profile, conducting that assessment in isolation of all other potential exposure pathways does a disservice to the public for awareness and transparency of the full scope of the anticipated potential risk from TCVP uses. *Id.* ¶ 34.

Thus, there are distinct advantages to the Agency's planned approach of using the Interim Decision process to develop the answer to the NRDC Petition. If the Agency were required to address the Petition separately, the Agency projects that the response date could be moved up by only six months: from September 2021 to March 2021. Decl. ¶ 34. The advantages described above would be lost, however, and in addition, the diversion of resources from the registration review to the Petition response would delay the Interim Decision from September 2021 to March 2022. *Id.* This delay will impair the interests of those who have concerns regarding the other TCVP uses. *Id.*

## III. NRDC HAS NOT SHOWN THAT EXTRAORDINARY REMEDY OF MANDAMUS IS WARRANTED

"Mandamus is warranted in those rare instances when the agency's delay is egregious." *PANNA*, 798 F.3d at 813. When all the factors described above are considered, NRDC has failed to show that this standard has been met. EPA's approach of preparing the response to the NRDC Petition through the process necessary to issue the Interim Decision on the review of all the TCVP registrations is reasonable, as is the Agency's planned schedule for completing this process. NRDC's request that the Agency be ordered to respond within 60 days is not tenable, given that a torsion study has just been submitted (but without the required protocol for EPA review, such that EPA has not yet determined whether the submitted study is an appropriate response to the Data Call-In). Any conclusion by EPA before that study has been evaluated could be subject to revision depending on the results of the study and its effect on the risk assessment. Furthermore, unless EPA has an adequate opportunity to consider the recently-submitted torsion study and to factor it into the risk assessment process, any administrative action to cancel or modify the registrations that EPA may take could be significantly impacted (both in timing and substance) by the new information, and later judicial review might be similarly impacted. Such an outcome would not advance the interests of NRDC, the general public, or the effective operation of the FIFRA program. Accordingly, the petition for a writ of mandamus should be denied.

## IV. THE SPECIFIC RELIEF REQUESTED BY NRDC IS PRECLUDED BY FIFRA

Finally, we note that the specific relief requested by NRDC is inappropriate. NRDC asks the Court to order EPA to take final action on its Petition within 60 days or less by: (1) issuing a denial; or (2) issuing a proposed decision to cancel all pet product registrations for TCVP to be followed by a final decision within one year. Under the statutory procedure, however, EPA cannot start cancellation proceedings simply by issuing a proposed decision to cancel.

To start cancellation proceedings, the Administrator must issue a notice of intent to cancel the registration. 7 U.S.C. § 136d(b). Before issuing such a notice, however, EPA must consider a series of factors identified in the statute. If a proposed notice of intent to cancel is prepared, the statute requires that EPA must share the notice with the USDA and the FIFRA Scientific Advisory Panel 60 days before sending it to the registrant or otherwise making the proposed notice public. *Id.*; *see also id.* § 136w(d). If either of these entities respond in writing within thirty days, EPA must publish in the Federal Register the proposed notice of intent to cancel; any comments from Agriculture; and EPA's response to such comments. *Id.* If, at the completion of this process, the Agency decides to proceed with the notice of intent to cancel, the final notice must include the reasons and factual basis for cancellation.

NRDC's proposed remedy does not account for this required process. Moreover, EPA cannot decide whether to issue a notice of intent to cancel until it has completed this statutory process and weighed the responses received. The statute does not give the Court the discretion to order EPA to skip the prescribed procedure or to predetermine the outcome of this process. Instead, a writ is limited to requiring the Agency to perform the allegedly required action by responding to NRDC's petition. *See PANNA*, 798 F.3d at 813. Therefore, EPA's response to the Petition (other than a denial) has to be limited to informing NRDC that the Agency has concluded that there are grounds to initiate the process for determining whether a notice of intent to cancel should be issued.

Moreover, if the final notice of intent to cancel notice is issued, the registrant or other appropriate party may request a hearing, which will be an adjudicatory proceeding before an administrative law judge ("ALJ") in accordance with EPA's rules governing cancellation hearings. 40 C.F.R. Pt. 164. The ALJ may allow discovery, *id.* § 164.50-51, and there will be a hearing at which testimony will be taken and exhibits submitted. *Id.* § 164.80-81. The ALJ will issue an initial decision, but that is subject to an administrative appeal before there is a final action by EPA. 40 C.F.R. § 164.101. The length of time required for such a process cannot be accurately predicted. Accordingly, any projected time frame for completing cancellation proceedings would be speculative.

Finally, as described above, both FIFRA and the relevant regulations give the registrant extensive legal rights in a cancellation proceeding. A cancellation order, if issued, is subject to judicial review. 7 U.S.C. § 136n(b). Thus, it is critical that EPA consider all available data, including the torsion study, in order to make a sound, science-based decision as to whether to proceed with a notice of intent to cancel the registrations at issue here.

Regardless, it would be inappropriate for this Court to order relief beyond the scope of the action allegedly unreasonably delayed—i.e., action on responding to NRDC's administrative petition. If NRDC believes that the response is less than complete, it may seek further relief from this Court. At present, however, the only question before the Court is whether the Agency should be ordered to respond by a date-certain. The relief requested by NRDC would go beyond the proper boundaries of a mandamus petition.

## CONCLUSION

For these reasons, NRDC's petition for a writ of mandamus should be denied. In the alternative, if the Court concludes that the writ should be granted, EPA should be allowed to respond to the Petition when the Interim Decision is signed, which EPA anticipates will be in September 2021.

Respectfully submitted,

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September 9, 2019

## STATEMENT OF RELATED CASES

Respondent EPA does not believe that any case is related to this matter according to the standard set forth under Circuit Rule 28-2.6. EPA disagrees with NRDC's assertion that *League of United Latin Am. Citizens v. Wheeler*, No. 17-71636 (9th Cir.) meets the Court's requirements for a related case.

s/ *Eileen T. McDonough*

## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Ninth Circuit Rule 21-2(c) because it does not exceed 30 pages, excluding the parts exempted by Federal Rules of Appellate Procedure 21(a)(2)(C) and 32(f).

The brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it was prepared in a proportionally spaced typeface using Microsoft Times New Roman 14-point font.

s/ *Eileen T. McDonough*

## CERTIFICATE OF SERVICE

I certify that the foregoing was served upon all counsel of record by the Court's CM/ECF system on September 9, 2019. All counsel of record are registered CM/ECF users.

s/ *Eileen T. McDonough*

**No. 19-71324**

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondent.

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# DECLARATION OF DR. MARY ELISSA REAVES IN SUPPORT OF RESPONDENT'S RESPONSE TO PETITION FOR WRIT OF MANDAMUS

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I, Dr. Mary Elissa Reaves, state the following:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based upon my personal knowledge and/or my review of information contained in the records of the United States Environmental Protection Agency ("EPA" or the "Agency") or supplied by current employees.

2. I am currently the Acting Director of the Pesticide Re-evaluation Division ("PRD") in EPA's Office of Pesticide Programs ("OPP"). I have worked for EPA for over 15 years. Since coming to the Agency in August 2003, I have served in various positions within OPP, including as Acting Branch Chief of the Risk Management and Implementation Branch IV ("RMIB4") of PRD from January 2011 to May 2011 and as Branch Chief of the Risk Assessment Branch IV of the Health Effects Division ("HED") from October 2011 to March 2015. I was the Acting Associate Director of the Antimicrobials Division ("AD") from March 2015 until September 2015 and was the Associate Director of HED from December 2016 until June 2019. I have been the Acting Director of the PRD since June 2019.

3. I am making this Declaration in support of EPA's opposition to the Petition for a Writ of Mandamus filed in the above captioned case.

4. PRD is the division assigned with the responsibility to develop EPA's regulatory position regarding the re-evaluation of conventional pesticides that are

currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Part of PRD's responsibility includes overseeing the periodic "registration review" of conventional pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

5. FIFRA, 7 U.S.C. §§ 136-136y, requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id.* The pesticide tetrachlorvinphos ("TCVP") was first registered in 1966 and is primarily used on livestock, poultry, and pets to control insects like fleas. TCVP is a member of the organophosphate ("OP") class of pesticides that are designed to kill target insects by inhibiting the enzyme acetylcholinesterase.

6. In 2006, EPA completed FIFRA reregistration and tolerance reassessment for TCVP and the OP class of pesticides. Tolerances are regulations that EPA establishes under section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") that set maximum allowable pesticide residue levels in food. As part of reregistration in 2006, EPA reassessed existing tolerances of TCVP to

ensure that they continued to meet the safety standard set forth in the FFDCA. Given ongoing scientific developments in the study of the OPs generally, EPA chose to prioritize the FIFRA section 3(g) registration review (the next round of re-evaluation following reregistration) of the OP class, which includes TCVP. The registration review of the OPs has presented EPA with numerous novel scientific issues. The Agency has raised these issues with multiple FIFRA Scientific Advisory Panel ("SAP") meetings since the completion of reregistration.

7. The TCVP registration review docket opened in June 2008 containing several documents including the Summary Document outlining potential data requirements for the re-evaluation of TCVP as well as the Environmental Fate and Effects Problem Formulation Document and Health Effects Scoping Document. These documents summarize information that EPA had on TCVP as of 2008 and provide the rationale for requiring the submission of additional data to satisfy specific data requirements. On November 26, 2008, following a 60-day comment period, the Agency issued its Final Work Plan and responses to the public comments.

8. The Generic Data Call-In ("GDCI") was issued December 29, 2009, requiring the submission of studies to inform the Agency's evaluation of risk from TCVP. Registrants are provided 90 days to submit an initial response to the GDCI explaining how they intend to fulfill the data requirements. The TCVP Task Force,

comprised of the TCVP registrants and their consultants, requested waivers in response to several of the GDCI-required studies. The Agency met with the TCVP Task Force to discuss these waiver requests, and ultimately accepted requests to waive several studies. The Agency denied several others based on its need to address certain human exposure scenarios, to understand the degradation of TCVP in certain conditions, and the failure of previous studies to establish toxicological endpoints and provide enough information to fulfill these requirements. In short, studies that were not waived were still considered outstanding data requirements needed for the Agency to assess potential ecological and human health risks from TCVP, and registrants remained obligated to submit the data pursuant to the terms of the GDCI. The TCVP Task Force committed to conducting the studies, and anticipated submission beginning March 2012.

9. The Agency received multiple requests from the TCVP Task Force to extend due dates of the remaining required studies. These extension requests were based on the difficulty the Task Force was experiencing in finding appropriate testing facilities as well as available lab capacity. Specifically, only a select number of laboratories conduct certain studies and there were other studies ahead in the queue at the available laboratories that the Task Force contracted to perform the studies. The Agency concluded that the rationales and proposed revised timeframes for submitting these data were adequate justification and granted these

time extensions. The Agency required the TCVP Task Force to submit interim reports to inform the Agency of their progress in conducting the studies. As studies were completed, incoming data were reviewed and were used in the development of the Agency's initial draft risk assessments.

10. On April 23, 2009, the Natural Resources Defense Council, Inc. ("NRDC") petitioned EPA to cancel all pet uses for TCVP, arguing, among other things, that EPA's human health risk assessment underlying EPA's 2006 Reregistration Eligibility Decision ("RED") for TCVP failed to adequately assess residential exposures from pet collars.

11. Concurrent with the TCVP Task Force's data development, the Agency expedited its review of the risk from pet uses. The Agency began with a summary of pet collar risk estimates from the RED, in order to frame the path forward for updating the pet use risk assessment in the February 2010 memorandum, *Tetrachlorovinphos, PC Code 083701, DP Barcode 346880: Summary of Pet Collar Risk Estimates*. This memorandum outlined the risk assessment methods that changed since the previous assessment for the TCVP RED and identified significant uncertainties that needed to be addressed in a new risk assessment. The Agency completed an updated TCVP assessment on the pet uses on November 5, 2014, *Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for*

*Tetrachlorvinphos* ("2014 Pet Products Assessment"), in advance of the Agency's comprehensive December 21, 2015 TCVP Draft Human Health Risk Assessment for registration review, in continued efforts to expedite a response to NRDC's petition.

12. Based on the November 5, 2014 Assessment, on November 6, 2014 EPA denied NRDC's April 23, 2009 administrative petition requesting cancellation of all pet uses of TCVP.

13. NRDC filed in January 2015 a petition for review of the denial in the Ninth Circuit Court of Appeals (Case No. 15-70025). While that litigation was pending, as part of EPA's ongoing registration review for TCVP and other OPs, EPA was conducting a new risk assessment for all uses (not just pet uses) of TCVP. Although that risk assessment was being conducted as part of the ongoing registration review and independently from the litigation on the denial of NRDC's administrative petition, EPA anticipated that it would consider many of the scientific issues raised in the litigation in preparing the risk assessment for TCVP registration review, and that the new risk assessment would likely differ in a number of ways from the earlier risk assessment relied upon by EPA in responding to NRDC's administrative petition. EPA therefore sought voluntary remand without vacatur in the litigation, which the Court granted on June 9, 2016.

14. On January 20, 2016, EPA published a Draft Human Health Risk Assessment for TCVP Registration Review dated December 21, 2015, for public comment in the Federal Register at 81 Fed. Reg. 3128 (Jan. 20, 2016). Although the TCVP registration review process was independent of the then-ongoing litigation concerning NRDC's 2009 administrative petition to cancel TCVP pet products, NRDC raised a number of issues in its August 5, 2015 Opening Brief in that litigation, including whether EPA should consider a particular study regarding exposure (*Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*, Journal of Exposure Science and Environmental Epidemiology, Davis, M. et. al. v.18, 564-570 (2008)) ("Davis Study"), and whether the TCVP in pet collars should be considered a liquid or a solid formulation. Thus, along with the Draft Risk Assessment for registration review, EPA also issued, on December 21, 2015, a document entitled "Tetrachlorvinphos (TCVP): Responses to Arguments Presented in the Natural Resources Defense Council, Inc.'s (NRDC) Aug. 5, 2015 Opening Brief in *NRDC v. EPA*, Case No. 15-70025 (9th Cir.)" (available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0308-0014). In that document, EPA explained that it could not fully respond to NRDC's claim regarding the Davis Study because it needed to be reviewed by the Human Studies

Review Board ("HSRB") prior to the Agency relying on it for risk assessment and decision-making.

15. The Davis Study includes 1) glove residue data collected by adult volunteers petting TCVP-treated dogs 2) plasma cholinesterase (ChE) measures from treated dogs 3) tee-shirt samples collected from children exposed to TCVP treated dogs and 4) urinary biomonitoring for adults and children exposed to TCVP treated dogs. However, for purposes of the TCVP risk assessment, the transferable residue data are the only data from the study that result in the potential for greater risks, are applicable to human exposures, or in the case of the urinary biomonitoring data, are useful given current scientific limitations (i.e., lack of a physiologically based pharmacokinetic (PBPK) model applicable to TCVP). While EPA proposed to rely only on the glove residue data (which did not involve children), there was still a need to have a review to determine if EPA may rely on the results of this data since these data were collected as part of broader research which did involve children.

16. 40 CFR 26.1703 prohibits EPA from relying on data from any research involving intentional exposure of any pregnant human subject (and therefore her fetus), nursing woman, or child, unless the EPA has: (a) obtained the views of the Human Studies Review Board (HSRB); (b) provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data; (c)

determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction to protect public health than could be justified without the data; and (d) published a full explanation of the decision to rely on the data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in item (c) was met.

17. EPA took the Davis Study to the HSRB in June 2016. The HSRB concluded that: "The research is scientifically sound and, if used appropriately, the pet fur transferable residue data from the rubbing protocol used in the study can provide useful information for evaluating potential exposures of adults and children from contact with dogs treated with tetrachlorvinphos containing pet collars." Per EPA's December 21, 2015 document setting forth responses to arguments raised in NRDC's Aug. 5, 2015 Opening Brief (cited in paragraph 14, above and *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0308-0014), "EPA would rely on these data (Davis Study) for regulatory decision making if HSRB determines that the study is scientifically valid and it meets appropriate human ethics requirements," since these data result in greater potential risks than those estimated using the amitraz pet collar residue transfer study (which EPA had relied upon in the previous risk assessments). Accordingly, post-application risks were assessed using the Davis Study data in the subsequent risk assessment.

18. In EPA's December 21, 2015 document setting forth responses to arguments raised in NRDC's Aug. 5, 2015 Opening Brief, the Agency also addressed whether the TCVP in pet collars should be considered a liquid or a solid formulation, explaining that per EPA's 2012 residential risk assessment standard operating procedures (SOPs, http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide), pet collar products are categorized as a liquid formulation, as supported by the best available science at the time of the SOP development. Data indicated that in pet collars, the active ingredient, which is embedded in the collar matrix, diffuses slowly through the matrix, controlling the amount of the active ingredient at the collar's surface. The active ingredient available on the surface of the pet collar then transfers from the collar to the animal's hair coat via embedded lubricants at the surface of the collar.

19. However, as NRDC pointed out in its Aug. 5, 2015 Opening Brief, the label for the Hartz UltraGuard Flea and Tick Collar for Dogs (EPA Reg. No. 2596-84) at that time stated that "as the collar begins to work, a fine white powder will appear on the surface." Taking these label statements into account and based upon further research suggesting that some pet collars may act by extrusion of the active ingredient from the collar matrix as a fine dust, EPA reconsidered the position that the TCVP pet collars are all liquid formulated products.

20. In response to NRDC's "liquid vs. solid" argument, in the TCVP Revised Human Health Risk Assessment for Registration Review, dated December 21, 2016, HED assessed pet collars using *assumptions* of varying ratios of liquid/dust in the collar in the exposure calculations to account for this *current uncertainty* in order to assess the impact it could have on the outcome of the assessment. This risk assessment was posted in the docket on December 29, 2016. (Available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0054). For the residential post-application exposure assessment, this means use of transfer coefficients (dermal exposures) and the fraction of active ingredient on hands from the transfer coefficient studies (hand-to-mouth exposures) specific to both liquid and solid formulation types. In the December 21, 2016 Revised Human Health Risk Assessment, risk estimates are provided *assuming* several different liquid/dust ratio formulations (1/99, 50/50, and 99/1). The 2016 Revised Human Health Risk Assessment indicates that there is at least a *60-fold difference* between the liquid/dust ratio of 99/1 and 1/99 liquid/dust ratio; the more TCVP that is in liquid form, the lower the risk concern.

21. EPA had anticipated that it would be in a position to respond fully to NRDC's administrative petition within 90 days of issuing the final revised Human Health Risk Assessment, and so stated that "intention and belief" in the context of the Agency's September 25, 2015 motion for remand in the prior litigation (Case

No. 15-70025). The final revised Human Health Risk Assessment was issued on December 21, 2016, 90 days after which was March 21, 2017. However, with the remaining uncertainty around the physical form of TCVP present in the pet collars, the Agency has been unable to fully respond to NRDC's administrative petition, and thus sent NRDC a letter on March 21, 2017 informing NRDC that EPA intends to address any risk-mitigation issues for the pet-care uses of TCVP in the context of registration review for the chemical.

22. Identifying the physical form of TCVP released from pet collars is likely to significantly impact the EPA's regulatory decision-making for this case. Regulatory decisions under FIFRA are subject to a risk-benefit standard. When EPA applies that standard, it first performs risk assessments to determine whether there are any risks of concern. If the assessment identifies risks of concern, EPA then must make a risk-management decision determining what, if anything, needs to be done to address the risks of concern. Because FIFRA calls for a risk-benefit standard, EPA can look at whether the benefits of a pesticide justify the risks associated with the pesticide; a pesticide causing risks of concern can meet the FIFRA standard if the pesticide use results in sufficient benefits. Even where risks of concern are determined not to be justified by benefits, EPA looks carefully at whether registration changes can sufficiently mitigate risks of concern either to allow EPA to conclude that the benefits now outweigh the (mitigated) risks, or that

the mitigated risk no longer exceeds the level of concern. The greater the level of risk, and the more the assessed level of risk exceeds EPA's level of concern, the harder it becomes for EPA to either make a positive risk-benefit determination allowing the registration to continue or to mitigate the risk to get it below the "risk of concern" level and the less likely it becomes that alternatives to cancellation can be found. In short, because the assumptions EPA used (liquid/dust ratios of 99/1, 50/50, and 1/99) in the 2016 risk assessment could potentially yield very different regulatory outcomes, it is prudent for the EPA to identify the form released from pet collars to ensure an appropriate regulatory decision.

23. EPA has determined that the most promising solution for identifying the physical form of TCVP released from each pet collar is to require the registrant to conduct a composition study in the form of a mechanical torsion study. The mechanical torsion is accomplished through twisting and stretching the collar multiple times to exaggerate the typical or expected movement of the collar against the animal to ensure release of the active ingredient contained in the collar matrix, in order to measure the maximum amount of dust that can be released from a pet collar.

24. EPA first discussed the utility of a mechanical torsion study with Hartz Mountain Corporation, the only remaining registrant of TCVP pet care products, in 2017. EPA specified that these data would reduce the uncertainty

around the liquid/dust formulation type issue and would provide necessary refinement to the TCVP post-application risk assessment.

25. Hartz maintains that due to the unique properties of TCVP (a solid), combining with one of the inert ingredients in the collar formulation to make a liquid, the physical chemical properties of those ingredients alone could be used to estimate the form of residues released from the collar. While Hartz has provided multiple exposure studies (one as recently as July 2019), all of the submitted exposure data are predicated on the physical chemical property argument that the TCVP pet collar behaves as a liquid.

26. Although EPA is reviewing the physical chemical property argument and data presented by Hartz, EPA issued a Data Call-In ("DCI") to Hartz on June 3, 2019 for conduct of the mechanical torsion study. DCIs are issued pursuant to FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B), which specifies that registrants have 90 days to submit an initial response to the DCI. The form EPA has developed for this initial response requires the registrant to identify how it intends to respond to the DCI.

27. In general, registrants have a number of options as to how to respond to a DCI, including voluntary cancellation, or agreement to conduct specified studies. If a registrant does not submit an adequate response within 90 days, then the registration would be subject to suspension pursuant to FIFRA section

3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B). The DCI in this case provides that Hartz is obligated to conduct the torsion study and submit the final report to EPA within 6 months after the 90-day deadline to identify how it intends to respond to the DCI (i.e., March 1, 2020). EPA determined that 6 months is reasonable based on the following considerations:

- A study protocol must be submitted to the EPA and reviewed by the Agency.
- The registrant must solicit laboratories to conduct the study.
- The lab must initiate and carrying out the study ("do the data").
- The lab must write and finalize the report.
- The data and final report must be reviewed for quality assurance (QA) in accordance with 40 CFR Part 160, and the report must include a QA Statement.

After these steps, the registrant must submit the final study report to EPA.

28. Hartz committed to conducting the torsion study in its August 28, 2019 90-day response. Along with the 90-day response, Hartz submitted a torsion study, but without first submitting a study protocol to the Agency for review, a step that had been required by EPA in the DCI to help ensure the results could be used for the purpose of risk assessment. Because EPA did not get to review the protocol before the study was conducted, the Agency expects that it will take six months to

review the protocol used by Hartz and to allow Hartz, if necessary, to address any inadequacies or conduct a new study (the same timeframe described in paragraph 27, above). At that time (March 1, 2020), the conduct of the torsion study will be considered completed.[1]

29. EPA could either (1) resolve the NRDC Petition as a discrete matter separate from the ongoing cancellation proceedings; or (2) address the pet collar registrations as part of the ongoing registration review process. Even if the Agency answers the petition first, the pet collar registrations will still have to be addressed in some respects during the registration review process. For the reasons set out below, it is more efficient for the Agency to address the pet collar registrations as part of the review of all TCVP registrations. Moreover, addressing the pet collar registrations as part of the ongoing review process instead of as a separate process will avoid the possibility that elements of the decision on pet products may have to be reassessed based on developments during the registration review process.

30. Issues of efficiency are particularly important for the Office of Pesticide Programs at this time. When registration review began in 2007,

[1] If EPA reviews the protocol and finds it to be wholly acceptable, then the Agency will already have the study in hand at that time. In that scenario, the timeframes described in this Declaration could possibly be shortened by two or three months.

approximately 725 registration review "cases"[2] that include approximately 1,140 pesticide active ingredients had to be reviewed by EPA by FIFRA's statutory deadline of October 2022, 7 U.S.C. §136(g)(1)(A)(iii)(I). While some cases have moved through the registration review process more quickly because additional data were not needed to conduct risk assessments, there have also been a number of cases that presented unique and challenging scientific questions, not dissimilar to the kinds of issues the Agency has faced in the TCVP review. As of now, the Office of Pesticide Programs has only 3 years remaining to complete decisions for nearly half of its cases (approximately 360).

31. In particular, inefficiencies will be avoided if EPA can include the pet products in the risk assessment and mitigation to be developed as part of the ongoing TCVP registration review because otherwise the Agency will have to conduct two separate risk assessments and mitigation decisions, resulting in duplicative efforts. As with any large organization, the staffing of project teams at the EPA can be dynamic due to competing priorities. It is therefore prudent to utilize the case-history, skills, and expertise of the team currently assigned to TCVP to complete the petition simultaneously with registration review; it means

[2] FIFRA's implementing regulations define a registration review case as being "composed of one or more active ingredients and all the products containing such ingredient(s)." 40 C.F.R. § 155.42.

the Agency wouldn't be faced with reassembling the team, working to fill a knowledge gap by integrating new team members, or duplicating efforts at a later date. Avoiding these inefficiencies will allow the Agency to more effectively complete all of its obligations with respect to reviewing TCVP registrations, as well as the many other pesticide active ingredients' registrations that must be addressed by October 22, 2022.

32. If EPA can address the pet product registrations as part of the ongoing TCVP registration review, EPA estimates that it can issue the TCVP registration review Interim Decision pursuant to 40 C.F.R. § 155.56 by September 2021 (if the initial review and any corrective action needed to the torsion study report are completed by March 2020). The response to the NRDC Petition can be issued at the same time as all necessary work particular to that Petition will have been completed in the course of preparing the Interim Decision. This 18-month period breaks down as follows:

- Three months to determine whether the completed study is scientifically acceptable;
- Three months to prepare a revised risk assessment for all TCVP registrations;
- Two months for public comment on the revised risk assessment;

- Six months for the Agency to address comments on the risk assessment; to hold discussion with stakeholders on possible mitigation requirements; and to prepare a Proposed Interim Decision (PID) for public comment;
- Two months for public comment on the PID;
- Two months to prepare the responses to comments, discuss with the registrants how they will implement any necessary changes to their registrations, and prepare the Interim Decision and the response to the NRDC Petition.

33. EPA could complete the Petition Response by March 2021 (one year from the completion of the initial review and any corrective action needed to the torsion study report) if the response was managed on a separate track from the ongoing TCVP registration review.

- Three months to determine whether the completed study is scientifically acceptable;
- Three months to prepare a revised risk assessment for the pet product registrations;
- If the risk assessment shows that there are no human health concerns, and EPA would thus be able to deny the NRDC Petition,

then EPA would be able to respond to the Petition within 30 days of completing the revised risk assessment.

- If there are potential risks of concern, EPA will need an additional six months to consider mitigation possibilities (such as decreasing the amount of TCVP in a flea collar) and the benefits associated with the use of the collars; determine the appropriate regulatory decision; negotiate with the registrant regarding necessary revisions to the registrations to reduce risk or request their voluntary cancellation of their registrations; and to prepare the final response.

34. While this approach would expedite the response by six months (from September 2021 to March 2021), it would also likely delay the Interim Decision for the registration review by six months (from September 2021 until March 2022). This delay is not in the interest of stakeholders, including the general public, who have concerns regarding the other TCVP registrations. Moreover, the public would not receive a full accounting of the anticipated risk from TCVP. While the pet use is an important component of the TCVP use profile, conducting that assessment in isolation of all other potential exposure pathways does a disservice to the public for awareness and transparency of the full scope of the anticipated potential risk from TCVP uses.

35. Allowing the EPA additional time to respond to the NRDC Petition concurrently with the Interim Decision in the ongoing TCVP registration review will improve the quality of the response and avoid any potential need for EPA to reconsider the response.

36. If EPA proceeds separately with respect to the NRDC Petition Response, there will be no public comment on the risk assessment or potential mitigation measures for the pet collar uses as part of the petition response. The Agency believes it beneficial to take comment on its regulatory decisions both to determine whether stakeholders or the public have additional information that warrants appropriate revisions to the decision, and to allow members of the public to participate in the regulatory process (which has a value of its own). In addition, the public will have the opportunity to comment on issues pertaining to pet products during the ongoing registration review. Issues may be raised that could require EPA to reconsider its response to NRDC's Petition.

37. Issuance of a decision regarding TCVP's registered pet uses independently (i.e., responding to the petition separately from registration review) does not preclude the potential need to revisit the acceptability of the pet uses in making a complete registration review decision. When determining whether pesticide tolerances meet the "reasonable certainty of no harm standard" in the FFDCA, EPA is obligated to aggregate all dietary and other non-occupational

exposures to a particular pesticide. While the pet use scenario itself does not fall under the review requirements of the FFDCA (because there is no dietary exposure from this type of use), exposure from pet products would have to be considered in the required assessment of aggregate risk associated with all TCVP products. The TCVP tolerance assessment would need to consider the aggregate risk to people who may be exposed to TCVP both from pet collars and through dietary exposures (and any other non-occupational exposures). Since TCVP is also used as a dermal and oral treatment on cattle, swine, and poultry, there is potential dietary exposure through the livestock and poultry use, for which there are tolerances under 40 CFR Part 180.252. If the aggregate risk from TCVP exposures is greater than the FFDCA allows, all contributing factors would be addressed to determine how to resolve the situation, including addressing the contribution of pet uses to aggregate risks. It is possible that modifying pet uses might be an appropriate solution to resolving an aggregate risk problem even if the pet care uses were otherwise acceptable when viewed on their own. Therefore, although it is possible that mitigation of the pet uses may be required as part of responding to the petition, mitigation for those uses may need to be revised again as a result of the registration review dietary assessment.

38. When EPA determines that a pesticide may pose an unreasonable risk, EPA could theoretically initiate a formal cancellation process without first talking

to pesticide registrants. However, EPA has found that it makes a great deal of sense to first see if issues can be resolved with registrants informally. Discussions with registrants can at times help identify alternative solutions to those proposed by EPA; at other times, discussions can facilitate a registrant's acceptance of the changes proposed by EPA. Where registrants are willing to make changes to their registrations that enable EPA to determine that the FIFRA standard would then be met, registrants submit appropriate applications for amended registration that EPA can grant and eliminate the need for formal cancellation. If EPA were to skip this discussion step, a registrant could propose alternative changes to the registration in a cancellation hearing, where EPA would be obliged to assess and respond to the changes during the hearing process (which would likely delay the completion of the hearing and could result in a change in Agency position at the hearing). Where registrants are not willing to make necessary changes, EPA will explore with the registrants whether they will agree to submit requests for voluntary cancellation, which can result in a quicker and less resource-intensive cancellation. If no agreement can be reached, EPA then would have to resort to the formal cancellation process which can be lengthy and resource-intensive.

39. In summary, EPA estimates that coupling the petition response to registration review would result in issuing an Interim Decision and a response to the NRDC Petition in September 2021, 18 months after it anticipates that the initial

review and any necessary corrections to the composition study will be completed. If the actions are uncoupled, EPA could reasonably complete the petition response in March 2021, and then could finalize registration review in March 2022. It would be preferable for the Agency to continue along its current trajectory for TCVP, anticipating issuing the Interim Decision concurrently with its response to the petition because: (1) it is far more efficient for the Agency to complete its entire risk assessment and risk management decision for TCVP at one time; (2) there would be no duplication of resources that could delay the TCVP registration review as well as other registration review actions; (3) the EPA believes it is desirable to make the public aware of the full scope of the anticipated potential risk from TCVP at one time; and (4) combining the petition response with the TCVP registration review will not significantly delay the response to the petition.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5th day of September 2019.

Dr. Mary Elissa Reaves